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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/801,951

03/17/2004

William F. DeGrado

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EXAMINER

CHONG, YONG SOO

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

02/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/801,951	Applicant(s) DEGRADO ET AL.	
	Examiner YONG S. CHONG	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2008.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15-49, 54-56, 62, 63 and 65-73 is/are pending in the application.
 4a) Of the above claim(s) 1, 15, 49, 54-56, 62, 63, 65 and 66 is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 16-48 and 67-73 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/21/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 10/27/08.

Claim(s) 2-14, 50-53, 57-61, 64 have been cancelled. Claim(s) 1, 15-49, 54-56, 62-63, 65-73 are pending. Claim(s) 1, 15, 49, 54-56, 62-63, 65-66 have been withdrawn. Claim(s) 16-48, 67-73 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and repeated below for Applicant's convenience.

With regard to the provisional obviousness double patenting rejection over Application No. 11/980,785, Applicant is reminded that a terminal disclaimer has not been submitted in the response filed on 10/27/08. Therefore, the provisional obviousness double patenting rejection is still maintained for reasons of record.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-48, 67-73 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-8, 11, 14-15, 20-22, 26 of U.S. Patent No. 7,173,102 B2.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the referenced claims recite a method of killing microorganisms by contacting a surface with a compound of formula II, whereas the instant claims recite the same compound of formula II in a method of treating a microbial infection in an animal.

A preferred polymer or oligomer in the referenced claims is represented by a compound of formula I, where X can be NR₃, NHNH (where R₃ is hydrogen), O, S; Y can be CO; both A and B are independently optionally substituted o-, m-, p-phenylene, or optionally substituted heteroarylene wherein one of A and B is substituted with a polar (P) group and a nonpolar (NP) group and the other of A and B is substituted with neither a polar nor a nonpolar group; NP can be R₄, -U-(CH₂)_p-R₄, wherein R₄ can be hydrogen, C₁-C₂ alkyl, C₃-C₁₈ branched alkyl, P is a polar group selected from hydroxyethoxymethyl or -U-(CH₂)_p-V, where U is O or S and V can be amino, guanidine; p is 0 to 8; and m is 2 to at least 500; R₁ is (i) -y-C, (ii) H, or (iii) R₁ and R₂ together are a single bond; R₂ is -x-(CH₂)_p-W wherein W is H, V, N-maleimide, phenyl optionally substituted with up to three substituents selected from the group consisting of

V, alkyl, carboxy, etc. Representative “heterocycles” include pyridine, cyclic guanidines, imidazole, piperidine, piperazine, etc. (claims 1, 4-8, 11, 14-15, 20-22, 26).

It would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer to an animal infected with a microorganism a pharmaceutical composition comprising a compound of formula I or II as disclosed by the referenced claims.

A person of ordinary skill in the art would have been motivated to administer to an animal infected with a microorganism a pharmaceutical composition comprising an oligomer of formula I because: (1) of general teaching that the disclosed oligomers inhibit the growth of microorganisms on a surface; (2) interpreting the term “substrate” broadly includes any surface in need of killing microorganism, such as the skin or internal organs; and (3) animals with a microbial infection is a species within the broad genus of substrates. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating a microbial infection in an animal by administering a composition comprising an oligomer of formula I.

Examiner notes that this is a typical genus/species situation. Once a *prima facie* case of obviousness is established, the burden is shifted to the Applicant for objective evidence for nonobviousness. See MPEP 2144.08.

Claims 16-48, 67-73 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 49-53 of copending Application No. 11/980,785. Although the conflicting claims are not

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identical, they are not patentably distinct from each other because both sets of claims recite a method of treating a microbial infection in an animal by administering a composition comprising an amphiphilic oligomer of formula II, in which the scope of formula II sufficiently overlaps so as to encompass the species election.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant argues against the obviousness double patenting rejection over US Patent 7,173,102 B2 because the instant claims are drawn to a method of treating a microbial infection in an animal, whereas the referenced claims are drawn to a method of killing microorganisms on a substrate, such as wood, cloth, or metal, both using the same oligomer as the active agent.

This is not persuasive because the obviousness rejection is over claims 1, 4-8, 11, 14-15, 20-22, 26 of U.S. Patent No. 7,173,102 B2, which recite the term "substrate" however do not specifically state the metes and bounds of the term. Therefore, Examiner has looked to the specification for the full scope of the term "substrate" as it refers to the claimed invention.

The reference teaches that the scope of the term "substrates" broadly includes any object that is exposed to or susceptible to bacterial or microbial contamination can be treated with the disclosed oligomers. In fact, testing of the bacterial efficacy has been performed in mammals with these polymers in water (col. 24, lines 57-64, example

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5-6). DeGrado et al. teaches a need to design these polymers with reduced toxicity to birds, fish, mammals, and other higher organisms. Furthermore, any object that is exposed to or susceptible to bacterial or microbial contamination can be treated with these polymers, particularly in food and health care, for example for the use in contact lenses. Both pets and agronomic animals are exposed to and harbor a variety of infectious pathogenic organisms that can cause disease in animals or humans (col. 27, lines 1-28).

Applicant also argue that a oligomer that functions as an antimicrobial agent, when attached or applied to a surface, such as wood or cloth, would not necessarily be effective in treating a microbial infection in an animal when administered to the animal by parental injection of the pharmaceutical composition. Applicant argue that the previously submitted Nicolau Declaration states that "a person of ordinary skill in the art would not necessarily expect a polymer shown to function as an antimicrobial agent when attached to or incorporated into an object to be effective in treating a microbial infection in an animal."

Therefore, since the term "substrate" encompasses those living organisms that are infected with microorganisms, it is obvious to one of ordinary skill in the art to use any routine and well known method of administering an active agent into the subject, which includes parental injection. The Nicolau Declaration does not present any factual evidence toward nonobviousness, but rather is merely an opinion statement. Applicant is reminded that the standard for obviousness is not absolute but a reasonable expectation of success. Since the claimed oligomers are known as antimicrobial

agents, it is obvious to use it on living organisms infected with microorganisms with a reasonable expectation of success, especially since the term “substrate” encompasses living organisms.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/YONG S. CHONG/
Primary Examiner, Art Unit 1617

YSC